DOCKET NO. CRD0918

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFEARANCES

Applicants: Donald F. DePalma et al.

Serial No.: 10/041,117 Art Unit: 3738

Filed : January 8, 2002 Examiner: Cheryl L. Miller

For : MODULAR ANEURYSM REPAIR SYSTEM

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September 27, 2005

(Date)

Carl J. Evens

Name of applicant, assignee, or Registered Representative

/Carl J. Evens/
(Signature)

September 27, 2005

(Date of Signature)

APPEALANT'S BRIEF ON APPEAL

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

1. REAL PARTY IN INTEREST

The real party of interest of the present application on appeal is the assignee, Cordis Corporation.

2. RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences known to appellant's legal representative or assignee, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

3. STATUS OF CLAIMS

Claims 1, 6, 20, 21 and 24 are pending in this application and have been finally rejected in the Final Office Action mailed March 29, 2005. Claims 2-5, 7-19 and 22-23 were cancelled without prejudice during prosecution. Each of Claims 1, 6, 20, 21 and 24 are on appeal.

4. STATUS OF AMENDMENT

A Response after Final Rejection was deposited with the Untied States Postal Service on June 29, 2005 in response to the Final Office Action mailed March 29, 2005. In an Advisory Action mailed July 21, 2005, the Examiner indicated that the response after Final Rejection failed to place the application in condition for allowance. Nonetheless, the Examiner entered the claim amendments made in the Response after Final Rejection.

5. SUMMARY OF CLAIMED SUBJECT MATTER

The invention embodied by the subject application on appeal is directed to a system for perentaneously repairing an aneurismal section of an artery, for example an abdominal aortic aneurysm and a thoracic aortic aneurysm. The system provides a means for overcoming the problems associated with anchoring and/or sealing bypass prostheses in highly angulated arterial sections, in diseased arterial sections, in too short arterial sections, in arterial junction areas and in larger arterial sections.

Claim 1 is the sole independent claim pending in the application. Antecedent support for each element of claim 1 is noted in the parenthesis following each claim element:

A system for bypassing an aneurysm comprising:

a first prosthesis, defining a single flow channel conduit having a proximal end and a distal end, (element 10 in Figure 1, page 16 paragraph [0074], page 17 paragraph [0075] and page 18 paragraph [0080]) including a self expanding lattice (element 40 in Figure 3, and element 40 in Figure 4, page 24 paragraphs [0015], [0016] and [0017]) and graft material covering at least a position of the self-expanding lattice, the graft material having longitudinally oriented pleats, (element 60 in Figure 5, page 26 paragraph [00114], page 27 paragraph [00116], [0017] [0018] and [0019], page 28 paragraphs [00120] [00121] and [00122]) the first prosthesis being configured to expand an artery into which it is positioned and anchor and seal the system within the artery; (Figure 1)

a compressible gasket positioned within the distal end of the first prosthesis, the compressible gasket comprising at least two apertures therein; (element 200 in Figure 1, Page 21 paragraphs [0090], [0091] and [0092] page 10 paragraph [0048] and Page 11 paragraph [0050]) and

at least two bypass prosthesis in fluid communication with the first prosthesis via the distal end of the first prosthesis, the at least two bypass prosthesis having proximal and distal ends, (elements 11a and 11b in Figure 1, page 16 paragraph [0074], page 23 paragraphs [00100], [00101] and [00102]) wherein the distal ends of the at least two bypass prosthesis are configured to anchor the at least two bypass prosthesis downstream of the aneurysm and the proximal ends of the at least two bypass prosthesis are configured to pass through the at least two apertures in the compressible gasket positioned in the distal end of the first prosthesis such that fluid flow paths are established, the compressible gasket being configured to engage and seal the at least two bypass prosthesis (page 16 paragraph [0074] and page 18 paragraph [0080]).

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Claims 1, 6, 21 and 24 were finally rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,843,160 to Rhodes (Rhodes).

2. Claim 20 was finally rejected under 35 U.S.C. §103(a) as being unpatentable over Rhodes in view of the applicant's specification.

3. Claims 1, 6, 20, 21 and 24 were finally rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,554,858 to Dereume et al. (Dereume) in view of U.S. Patent No. 5,476, 506 to Lunn (Lunn).

7. ARGUMENT

1. Are claims 1, 6, 21 and 24 anticipated under 35 U.S.C §102(b) by U.S. Patent No 5,843,160 to Rhodes?

Claims 1, 6, 21 and 24 are not anticipated by Rhodes. Rhodes discloses a system for bypassing an aneurysm or aneurysms at a bifurcation in a vessel. The prosthesis for aorto-iliac aneurismal disease includes a common, stent-supported sleeve section having an expandable outer balloon for engaging and trapping the thrombus in the aneurysmal space in the abdominal aorta, and a pair of stent supported sleeve limb sections. The limb sections are

connected to the common section to provide a passage for blood to flow through the prosthesis. Sealing rings are utilized to prevent leakage.

Anticipation exists only if all of the elements of the claimed invention are present in a system or method disclosed, expressly or inherently, in a single prior art reference. Therefore, if it can be shown that there is one difference between the claimed invention and what is disclosed in the single reference, there can be no anticipation.

If one were to make the argument that each of the elements of Claim 1 is anticipated by Rhodes, one would have to equate the common, stent supported sleeve section of Rhodes with the first prosthesis of Claim 1. Equating these elements is clearly erroneous. In Claim 1, the first prosthesis comprises a self-expanding lattice covered by graft material. In Rhodes, stents are only utilized on the ends of the sleeves and not throughout the entire length of the component. Accordingly, this is one difference.

Since appellants have shown that there is at least one difference between the claimed subject matter and the cited reference, there can be no anticipation and the rejection in light of Rhodes is without merit and should be overruled.

2. Is Claim 21 unpatentable under 35 U.S.C. §103(a) over Rhodes in view of applicant's specification?

Claim 21 is not obvious in view of Rhodes. A claimed invention is unpatentable if the difference between it an the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. §103(a) (Supp. 1998); see *Graham v. John Deere Co.,* 383 U.S. 1, 14, 148 USPQ 459, 465 (1966). The ultimate determination of whether an invention is or is not obvious is a legal conclusion based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level or ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. See Graham, 383 U.S. at 17-18, 148 USPQ at 467; *Miles Labs, Inc., v. Shandon Inc.,* 997 F,2d 870, 877, 27 USPQ2d 1123, 1128 (Fed Cir. 1993).

The MPEP, in section 706.02(j), sets forth the basic criteria that must be met in order to establish a *prima facie* case of obviousness:

> "To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d, 488,20 USPQ 2d 1438 (Fed.Cir. 1991). See MPEP §2143 – §2143.03 for decisions pertinent to each of these criteria"

Section 2143.03 of the MPEP clarifies certain criteria in section 706.02(j).

> "To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490F.2d 981, 180 USPQ 580 (CCPA 1074). "All words in a claim must be considered in judging the patentablity of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5USPQ2d 1596 (Fed. Cir. 1988)."

There is nothing in Rhodes and Applicant's own teachings that forms the basis of this rejection. As described with respect to first issue, Rhodes fails to disclose the first prosthesis as claimed in claim 1. In addition, there is simply no teaching or suggestion in Rhodes of the first prosthesis of the claimed invention. As set forth above, all of the claim limitations must be taught

or suggested by the prior art and this the Examiner has not done. Accordingly, the rejection is without merit and should be overruled.

3. Are Claims 1, 6, 20, 21 and 24 unpatentable under 35 U.S.C. §103(a) over U.S. Patent No. 6,554,858 to Dereume et al. (Dereume) in view of U.S. Patent No. 5,476,506 to Lunn?

Claims 1, 6, 20, 21 and 24 are patentable over the combination of Dereume and Lunn.

Dereume discloses an intraluminal prosthesis. The intraluminal prosthesis comprises a tubular trunk that is divided into several axial channels. The several axial channels are adapted to receive stent grafts. The tubular trunk comprises a tubular stent and a sleeve. The sleeve has in its central part, diametrically opposite parts which are joined together. The sleeve delimits the internal cavity of the tubular trunk element and, by virtue of its shape, it forms, inside the latter, an arrangement of two axial channels which divide the cavity into two parallel conduits which have a shape similar to vascular conduits and which are sealed off in a elliptical manner from one another and in each case, the aneurism.

Lunn discloses a graft. The graft comprises a thin walled hollow cylinder having a central portion and end portions. The end portions are provided with a series of longitudinally extending pleats. This allows for diameter control. The central portion is provided with a series of circumferential crimps. This is for length control. Stents are used in the end sections to expand and sandwhich the walls of the end portions between the stents and the vessel wall (see Figures 4 and 5A).

The MPEP, in section 706.02(j), sets forth the basic criteria that must be met in order to establish a prima facie case of obviousness:

> "To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The

> teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d, 488,20 USPQ 2d 1438 (Fed.Cir. 1991). See MPEP§2143 – §2143.03 for decisions pertinent to each of these criteria"

Section 2143.03 of the MPEP clarifies certain criteria in section 706.02(j).

> "To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490F.2d 981, 180 USPQ 580 (CCPA 1074). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5USPQ2d 1596 (Fed. Cir. 1988)."

The references, whether taken alone or in combination fail to disclose or even remotely suggest the claimed invention. In Claim 1, four separate elements are claimed; namely, a first prosthesis, a compressible gasket positioned in the distal end of the first prosthesis and at least two bypass prosthesis. In Dereume, the sleeve has two parts (5 and 6 in Figure 1) that are affixed to one another to create channels. In the claimed invention, a compressible gasket is positioned within the distal end of the first prosthesis. The compressible gasket has at least two apertures therein. Lunn fails to cure this deficiency.

In addition, the first prosthesis comprises a self-expanding lattice covered by graft inserted having longitudinally oriented pleats. Lunn fails to disclose or even remotely sugest this feature. Lunn has pleats, but not pleats of a graft covering a self-expanding lattice. In Lunn, only the ends have stents or self-expanding lattices.

Accordingly, the combination of references fails to teach or suggest all of the claimed features. Therefore, a *prima facie* case of obviousness has not been met.

In establishing a basis for denying patentability of an invention, the initial burden rests with the Examiner. *In re Piasecki*, 745 F.2d 1468; 223 USPQ 785 (Fed. Cir. 1984). Thus, it is incumbent upon the Examiner to provide a reason why of ordinary skill in the art would have been led to modify a prior art reference or to combine teachings in order to arrive at the claimed invention. *Ex Parte Clapp*, 227 USPQ 972 (BPAI 1985). Moreover, this reason must stem from some teaching, suggestion or inference in the prior art or knowledge generally available and not from the applicant's disclosure. *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044; 5 USPQ 2d 1434 (Fed. Cir. 1988). As stated in *W.L. Gore and Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540; 220 USPQ 303 (Fed. Cir. 1983):

> [to imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.

The Federal Circuit's case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for showing of the teaching or motivation to combine prior art references. See, *e.g. C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998) (describing "teaching or suggestion or motivation [to combine]" as an "essential evidentiary component of an obviousness holding"); *In re Rouffeet*, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) ("the Board must identify specifically...the reasons one of ordinary skill in the art would have been motivated to select the references and combine them"; *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (Examiner can satisfy burden of obviousness in light of combination "only by showing some objective teaching [leading to the combination]"); *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988) (evidence of teaching or suggestion "essential" to avoid hindsight); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 297, 227 USPQ 657, 667 (Fed. Cir. 1985) (district court's conclusion of obviousness was error when it "did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the property of combination"). See also Graham, 383 U.S. at 18, 148 USPQ at 467 ("strict observance" of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability—the essence of hindsight. See, *e.g., Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 UASPQ 543, 547 (Fed. Cir. 1985) ("The invention must be viewed not with the blueprint drawn by the inventor,

but in the state of the art that existed at the time.") In this case, it appears that the Examiner has fallen into the hindsight trap."

Assuming for the sake of argument that the combination of references does in fact suggest all of the claimed elements, there is simply no motivation to have combined the references. Therefore, based upon the arguments outlined above, it is clear that this obviousness rejection is without merit and should be overruled.

Applicants submit that the above remarks and supporting information establish that the Examiner's cited grounds for rejections are improper and as such should be reversed. Applicants thus respectfully request that the Board of Patent Appeals and Interpretation find that the remaining claims are in condition for allowance, with instructions to the Examiner to allow the claims.

Respectfully submitted,

/Carl J. Evens/

By_____

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8. CLAIMS APPENDIX

Claim 1. A system for bypassing an aneurysm comprising:

a first prosthesis, defining a single flow channel conduit, having a proximal end and a distal end, including a self-expanding lattice and graft material covering at least a portion of the self-expanding lattice, the graft material having longitudinally oriented pleats, the first prosthesis being configured to expand an artery into which it is positioned and anchor and seal the system within the artery;

a compressible gasket positioned within the distal end of the first prosthesis, the compressible gasket comprising at least two apertures therein; and

at least two bypass prostheses in fluid communication with the first prosthesis via the distal end of the first prosthesis, the at least two bypass prostheses having proximal and distal ends, wherein the distal ends of the at least two bypass prostheses are configured to anchor the at least two bypass prostheses downstream of the aneurysm and the proximal ends of the at least two bypass prostheses are configured to pass through the at least two apertures in the compressible gasket positioned in the distal end of the first prosthesis such that a fluid flow paths are established, the compressible gasket being configured to engage and seal the at least two bypass prostheses to the first prosthesis.

Claim 6. The system of claim 1 wherein the at least two bypass prostheses each comprise a stent and graft material communicating with the stent.

Claim 21. The system of claim 1 wherein the compressible gasket is substantially impervious to fluid thus creating a seal between the first and the at least two bypass prostheses.

Claim 24. The system of claim 21 wherein said first prosthesis is of sufficient length to extend from a healthy region of an infrarenal neck into an aneurysm and the compressible gasket is engaged with the at least two bypass prostheses at a position along the first prosthesis that is configured to be disposed within an aneurysm.

9. EVIDENCE APPENDIX

Not Applicable

10. RELATED PROCEEDINGS APPENDIX

Not Applicable

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(Date of Signature)

AUTHORIZATION TO CHARGE DEPOSIT ACCOUNT

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Alexandria, VA 22313-1450

Dear Sir:

Attached is an Appeal Brief for the above-captioned patent application.

Please charge Deposit Account No. 10-0750/CRD0918/CJE in the name of Johnson & Johnson in the amount of $500.00, representing the cost of filing a Brief on Appeal in the above-captioned matter.

The Commissioner is hereby authorized to charge any additional fees which may be required to Account No. 10-0750/CRD0918/CJE. This Authorization is being submitted in triplicate.

Respectfully submitted,

/Carl J. Evens/

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